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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,531	09/18/2001	Zoe Weaver	689290-77	8649

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EXAMINER	
SMITH, CAROLYN L	
ART UNIT	PAPER NUMBER
1631	6

DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/954,531	WEAVER, ZOE	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sh et with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet* .

Continuation of Attachment(s) 6). Other: CRF Problem Report (2 pages) Paper No. 7.

DETAILED ACTION

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825, because it lacks a Sequence Listing on a computer readable form or CD-ROM and SEQ ID Nos cited along with each sequence that matches the application specification. Applicants are reminded that a CD-ROM sequence listing submission may replace the paper and computer readable form sequence listing copies. Applicant(s) are required to submit a new computer readable form sequence listing, a paper copy, or CD-ROM for the specification, statements under 37 CFR § 1.821 (f) and (g). Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office Action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, drawn to a process of identifying an agent that modulates cancer-related gene activity, classified in class 435, subclass 7.1. If this Group is elected then the below summarized sequence election is also required.

II. Claim 18, drawn to a process for identifying an agent via administering to an animal, classified in class 435, subclass 6. If this Group is elected then the below summarized sequence election is also required.

III. Claims 19-24, drawn to a process for determining the cancerous status of a cell via comparison of gene expression, classified in class 436, subclass 64. If this Group is elected then the below summarized sequence election is also required.

IV. Claims 25-28, drawn to a process for determining if a test gene is a cancer initiating or facilitating gene, classified in class 435, subclass 6. If this Group is elected then the below summarized sequence election is also required.

V. Claims 29-30, drawn to a process for determining if a test gene is a cancer suppressor gene, classified in class 435, subclass 6. If this Group is elected then the below summarized sequence election is also required.

VI. Claims 31-35 and 37-42, drawn to a process for treating and protecting from cancer, classified in class 436, subclass 64. If this Group is elected then the below summarized sequence election is also required.

VII. Claim 36, drawn to a method for producing a product, classified in class 702, subclass 19. If this Group is elected then the below summarized sequence election is also required.

VIII. Claims 43-46, drawn to profiling of functionally related genes, classified in class 435, subclass 6. If this Group is elected then the below summarized sequence election is also required.

Sequence Election Requirement Applicable to All Groups:

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid/polypeptide sequences, the Applicants must further elect a single amino acid/polypeptide sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic acid sequence (See MPEP 803.04). It is noted that the multitude of sequence submissions of examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement. In recognition of the profiling of functionally related genes in Group VIII, if Group VIII is chosen, then it is asked that the Applicant selects one sequence initially from which examination may begin.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a specie election requirement.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different processes and methods, restriction is deemed to be proper for Groups I-VIII because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I-VIII are directed to processes and methods that comprise different means and produce different results/goals. Groups I and II both identify agents using putative modulating materials initially, but Group I identifies an agent for modulating a cancer-related gene via cell contact while Group II identifies an anti-neoplastic agent via administration to an animal. Group III determines the cancerous status of a cell via comparison of gene expression which differs in its goal from the other Groups. Group IV determines if a test gene is a cancer-initiating or facilitating gene using agents already known to modulate activity and concentrates on the decrease of gene expression. Group V determines if a test gene is a cancer suppressor gene using agents already know to modulate activity and concentrates on the increase of gene expression. Group VI treats and protects an entity from cancer which differs from the goals of the other Groups. Producing a data-collected product in Group VII renders itself as a unique invention as no other Group contains such a product. Profiling of functionally related genes as in Group VIII is not found among the other Groups. These distinct processes and methods are often separately characterized and published in literature and would add undue search burden if they were all examined together. Thus, they are considered distinct invention types for restriction purposes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is

(703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

ARDIN H. MARSCHEL
PRIMARY EXAMINER

January 23, 2003